

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 5 77 WEST JACKSON BOULEVARD CHICAGO, IL 60604-3590

DEC 14 2006

REPLY TO THE ATTENTION OF:

AE-17J

Anthony C. Sullivan Barnes & Thornburg, LLP 11 South Meridian Street Indianapolis, IN 46204-3535

Re: <u>December 8, 2005 Self-Disclosure Letter for Mead Johnson Mount</u>

Vernon Facility

Dear Mr. Sullivan:

We are in receipt of the December 8, 2005, self-disclosure letter submitted by you in which you have voluntarily disclosed that Mead Johnson's facility in Mount Vernon, Indiana (Facility), was in violation of the applicable provisions of 326 IAC 12 et seq. and 40 C.F.R. Part 60, Subpart Ec. The disclosure was made pursuant to United States Environmental Protection Agency's (U.S. EPA) policy, "Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations," referred to as the "Audit Policy" (see 65 Fed. Reg. 19618 (2000)).

- U.S. EPA has determined that based on the information provided in the document listed above, Mead Johnson's self-disclosure comports with the requirements in U.S. EPA's Audit Policy. In reaching this determination, U.S. EPA has considered the nine criteria in the Audit Policy, as set forth below.
- 1. <u>Systematic Discovery</u>: U.S. EPA evaluates whether the violation was discovered by means of a systematic, internal, environmental audit or through a compliance management system that reflects due diligence in preventing, detecting and correcting violations.

Mead Johnson stated that it discovered the violation through an internal investigation into the activity involving the incinerator at the Facility.

2. <u>Voluntary Discovery</u>: U.S. EPA evaluates whether the violation was identified through an activity which your company was legally required to perform and/or report, such as under a federal or state statute, regulation or permit, judicial or administrative order or consent agreement.

Mead Johnson stated that the investigation was undertaken voluntarily.

3. <u>Prompt Disclosure</u>: Disclosure of the violation is within twenty-one (21) days of the date of the initial discovery, or such shorter period as may be provided by law. If not, the

company must provide reasons for the delay.

Mead Johnson determined that there was a potential violation on November 21, 2005. Mead Johnson then disclosed the violation on December 8, 2005, by letter to Jodi Swanson-Wilson, Office of Enforcement and Compliance Assurance, U.S. EPA.

4. <u>Independent Discovery and Disclosure</u>: U.S. EPA must evaluate (A) whether the company previously received notification of a citizen or third party suit for the violation disclosed or a closely related violation; and (B) whether the company previously received notice of commencement of a federal, state or local agency inspection or investigation or received an information request from a federal state or local agency.

Mead Johnson stated that the discovery was independent of a government enforcement action or inspection, or a third party complaint.

5. <u>Correction and Remediation</u>: U.S. EPA must evaluate measures taken to correct or remediate the violation. If more than sixty days will be needed to correct the violation, the company must provide a full explanation including opinions of any technical or engineering expert relied upon to arrive at that estimate as well as the estimated length of time it took or will take to complete these measures.

Mead Johnson stated that it corrected the violation by no longer operating the incinerator in a manner that would trigger the co-fired combustor exemption of 40 C.F.R. § 60.51c, Subpart Ec. At this time, Mead Johnson intends to operate the incinerator as a pathological waste incinerator, also regulated by Subpart Ec, but falling within the pathological waste incinerator exemption of 40 C.F.R. § 60.50c(b). Mead Johnson has submitted a "Notification of Pathological Waste incinerator Exemption" for the incinerator in building 101 of the Facility as required by 40 C.F.R. § 60.50c(b), Subpart Ec and will comply with the reporting provisions of this subpart.

6. <u>Prevent Recurrence</u>: U.S. EPA evaluates measures taken or to be taken to ensure that the violation disclosed will not be repeated, including improvements made to the company's auditing or compliance management procedures to prevent recurrence of the violation.

Mead Johnson stated that it will ensure compliance with any applicable regulations before re-starting operation of the incinerator. Med-Johnson will take all necessary steps to comply with the recording and record keeping requirements imposed (including a modification of its permit, if necessary.)

7. <u>No Repeat Violations</u>: U.S. EPA must evaluate information on the compliance status at the facility or any parent organization. Under the repeat violations exclusion, the same or a closely-related violation must not have occurred at the same facility within the past three years, or within the past five years if the violation occurred as part of a pattern of violations at

multiple facilities owned by the same entity.

Mead Johnson stated that neither the same violation, nor any closely related violation, has occurred within the prior three years.

8. Other Violations Excluded: U.S. EPA must consider whether the violations (A) resulted in any serious actual harm to human health or the environment or may present any form of endangerment to public health or the environment, or (B) violate the specific terms of any administrative or judicial order or agreement.

Mead Johnson stated that the violation neither resulted in any serious actual harm to human health and the environment, did not present an imminent and substantial endangerment to human health and the environment, and did not violate any specific term of any order, consent agreement, or plea bargain.

9. <u>Cooperation</u>: U.S. EPA must consider whether Mead Johnson cooperated as required by U.S. EPA.

U.S. EPA believes that Mead Johnson has been cooperative in this process and has provided the information necessary for U.S. EPA to determine the applicability of the Audit Policy.

After considering these criteria, U.S. EPA has determined that based on the information provided by Mead Johnson pertaining to its Mount Vernon, Indiana facility in its December 8, 2005 self-disclosure comports with the requirements in U.S. EPA's Audit Policy. U.S. EPA has also determined that the economic benefit derived by Mead Johnson in committing the disclosed violations was minimal and that a full waiver of the gravity-based penalty is acceptable. Therefore, U.S. EPA does not intend to pursue additional actions to resolve these violations at this time.

This letter is in no way intended to preclude U.S. EPA or any other regulatory agency from pursuing enforcement action for violations not disclosed by Mead Johnson in its December 8, 2005, self-disclosure or if it is later determined that some of the criteria of the Audit Policy were not met.

If you have any questions, please contact Rodrigo Valle of my staff at (312) 886-1474.

Sincerely,

Stephen Rothblatt, Director Air and Radiation Division